UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 15-CIV-61210-BLOOM/VALLE

JOSEPH T. MINK,

Plaintiff,

v.

SMITH & NEPHEW, INC.,
a foreign corporation,

Defendant.
_____/

ORDER ON MOTION TO DISMISS

This cause is before the Court upon Defendant Smith & Nephew, Inc's Motion to Dismiss Plaintiff's Second Amended Complaint ("Motion"), ECF No. [32]. The Court has considered the Motion, all supporting and opposing filings, including Plaintiff Joseph Mink's Response ("Pl. Resp."), ECF No. [33], and Defendant's Reply ("Def. Reply"), ECF No. [36], and has reviewed Plaintiff's Second Amended Complaint ("SAC"), ECF No. [29], and the record in this case. Being fully advised, the Motion is **GRANTED** for the reasons set forth below.

I. BACKGROUND

The instant Motion raises issues identical to those raised with respect to Plaintiff Joseph Mink's Amended Complaint, which was dismissed with leave to amend on November 18, 2015. *See Mink v. Smith & Nephew, Inc.*, No. 15-CIV-61210, 2015 WL 7356285 (S.D. Fla. Nov. 18, 2015). Consequently, a recitation of the underlying facts is repetitive but necessary.

On June 6, 2011, Plaintiff Joseph Mink ("Plaintiff" or "Mink") underwent a hip-replacement surgery. *See* SAC at ¶ 19. Shortly thereafter, Mink began experiencing elevated

chromium and cobalt levels in his blood, metal ions which are toxic to the human body at certain levels. *See id.* at ¶¶ 28-29, 32. Mink suffered deleterious effects from the large content of metal ions in his bloodstream, including eye problems and an enlarged left inguinal lymph node near the operative site that had to be surgically removed. *Id.* at ¶¶ 28-32. Mink now brings this action for damages stemming from this harm.

Defendant Smith & Nephew, Inc. ("Defendant" or "S&N") develops and manufactures joint replacement systems, including a metal-on-metal hip resurfacing prosthesis comprised of a femoral head and hemispherical acetabular cup, known as the "Birmingham Hip Resurfacing System" (the "BHR," "BHR System," or "System"). *See id.* at ¶¶ 6-8. Prior to its commercial distribution, the BHR underwent premarket approval ("PMA") by the Food and Drug Administration ("FDA"). *Id.* at ¶ 9. The BHR received conditional approval on May 9, 2006, which permitted S&N to distribute the BHR in accordance with certain conditions imposed by the FDA, including FDA approval of supplemental changes affecting the safety or effectiveness of the device, post-approval reporting requirements, and adverse reaction and device defect reporting. *Id.* at ¶¶ 9-10, 38-42; Exhibit "A" to SAC, May 9, 2006, FDA Approval Letter ("PMA Approval Letter"), ECF No. [29–1] at 1, 6-9.

After being diagnosed as requiring a hip replacement, Mink's orthopedic surgeon scheduled the surgery with a competing manufacturer's system. SAC at ¶¶ 11-12. Upon learning of S&N's BHR System through advertisements, Mink contacted S&N, and was directed by S&N to Jason Weisstein, M.D. ("Dr. Weisstein"), a local orthopedic surgeon purportedly acting as either the express or implied agent or representative of S&N. *Id.* at ¶¶ 12-13. Mink met with Dr. Weisstein, who advised Mink of the BHR's FDA premarket approval and informed Mink that if he agreed to use the BHR, he would be included in S&N's 10-year post approval

study, where he would be regularly monitored with follow-up visits and testing for 10 years at no personal cost (the "BHR Study" or "Study"). *Id.* at ¶ 14. The Study included assessments of renal functions, as well as blood samples to monitor metal ions in the blood over the long term. *Id.* Based on these representations concerning the BHR Study, Mink believed that he would be more closely monitored than if he had the surgery performed elsewhere. *See id.* at ¶ 15. Accordingly, Mink agreed to undergo the hip replacement surgery using the BHR System and signed a form consenting to his involvement in the BHR Study. *Id.* at ¶ 16; Exhibit "B" to SAC, Consent to Participate in a Clinical Research Study Entitled: A Prospective, Multi-Centered Study of the Birmingham Hip Resurfacing System ("Consent to Participate Form"), ECF No. [29-2] at 2-10.

Approximately seven weeks after the surgery, on August 1, 2011, Dr. Weisstein advised Mink that he was relocating and that the follow-ups under the BHR Study at his office would be discontinued. *Id.* at ¶¶ 22; Exhibit "C" to SAC ("August 1st Weisstein Letter"), ECF No. [29-3] at 2. Stating that he was in communication with S&N regarding Mink's continued involvement in the BHR Study, Dr. Weisstein told Mink that he would arrange a convenient, local follow-up. August 1st Weisstein Letter at 2. On August 18, 2011, Dr. Weisstein made good on his promise and informed Mink that S&N had arranged for him to continue as a participant in the BHR Study with Gregory Martin, M.D. ("Dr. Martin"). SAC at ¶ 23; *see also* Exhibit "D" to SAC ("August 18th Weisstein Letter"), ECF No. [29-4] at 2. Assuming that the visit to Dr. Martin would be covered by the BHR Study, Mink was surprised when Dr. Martin knew nothing about him or his participation in the BHR Study, and was even more surprised when he received a bill for his visit. *See* SAC at ¶ 25. On May 14, 2012, S&N informed Mink that it could not locate a clinical site to continue follow-up study activities and was, therefore, terminating him from the Study.

See id. at ¶ 26; *see also* Exhibit "E" to SAC ("Termination Letter"), ECF No. [29-5] at 2 (noting that S&N was "releasing [Mink] of any/and all follow-up obligations per protocol"). At no point did Mink wish to be terminated from the Study, particularly in light of the ever-increasing chromium and cobalt levels in his blood. *See id.* at ¶ 28. Due to the rising toxicity in his blood, Mink was obligated to monitor the situation at his own expense. *Id.* at ¶ 29. On November 17, 2014, Mink underwent revision surgery to remove the BHR System. *Id.* at ¶ 37.

As noted, the injurious effects of the BHR prompted Mink to initiate this action, where he now asserts that the BHR System was defective because it failed to comport with FDA requirements and failed to follow the FDA's Current Good Manufacturing Practice provisions "to insure that the finished BHR will be in specific compliance with 21 U.S.C. § 360(e)," believing that a properly manufactured BHR System "would not cause immediate and toxic levels of chromium and cobalt in [his] blood." *See* SAC at ¶ 33. Although Mink cannot presently identify how the BHR System is noncompliant with 21 U.S.C. § 360(e), he, nevertheless, believes that the installed System was not manufactured to the specifications required by 21 U.S.C. § 360(e) based on the immediacy of the metal poisoning.[1] *Id.* at ¶ 34. Mink also insinuates that his termination from the Study was, in part, an attempt to avoid reporting requirements. *Id.* at ¶ 35 (noting that S&N would have been required to file an "Adverse Reaction and Device Defect Report" with the FDA).

Based on the foregoing, Mink brings four claims: (1) negligence; (2) strict products liability; (3) breach of contract; and (4) misrepresentation. *See id.* at ¶¶ 43-89.

[1] The Court notes that 21 U.S.C. § 360(e) concerns registration numbers assigned to persons and products under the FDCA and is seemingly irrelevant to Mink's claims. *See id.* (titled "Registration number; uniform system for identification of devices intended for human use").

Mink's common-law negligence claim ("Count I") arises from S&N's purported breach of its duty to comply with and not deviate from the PMA requirements contained in the BHR System's FDA approval, as well as "other federal statutory and regulatory requirements that applied to the BHR System." *See id.* at ¶¶ 43-45. Specifically, Mink discloses a slew of alleged violations of 21 C.F.R. §§ 814.82, 814.84, 820.30, 820.80, 820.100, and 820.198, which are brought "only to the extent that they are parallel to and not different from or in addition to the requirements of federal law." *See id.* at ¶ 51. Mink's strict products liability claim ("Count II") similarly relies on S&N's purported violation of 21 C.F.R. § 814.80 and other federal regulatory law by deviating from the manufacture specifications approved by the FDA in its PMA Approval Letter. *Id.* at ¶ 59. Based on these violations, Mink concludes that the BHR System was defective and unreasonably dangerous when it left S&N's possession. *See id.* at ¶ 59.

Mink also brings claims for breach of contract ("Count III") and negligent misrepresentation ("Count IV"). *See generally id.* at ¶¶ 66-89. Under his theory of breach of contract, Mink contends that S&N failed to comply with the terms of the Consent to Participate Form by terminating him as a Study participant and declining to transfer Mink to another approved doctor to continue the Study. *Id.* at ¶¶ 74-76. Mink's claim for negligent misrepresentation travels under a similar theory, namely, that S&N misrepresented to Mink that he would be a continuing BHR Study participant and would receive the benefits thereof for a minimum of 10 years at no out-of-pocket cost to him. *See id.* at ¶¶ 81-88. He alleges that these misrepresentations induced him to abandon the competitor's product and, instead, sign up for implantation of the BHR. *See id.* Although the representations related to Counts III and IV were made by Dr. Weisstein, Mink contends that Dr. Weisstein was S&N's trained and approved doctor, who was acting as S&N's expressed and implied agent. *Id.* at ¶¶ 66-68, 70, 81.

Alternatively, Mink claims that S&N ratified Dr. Weisstein's representations and commitments. *See, e.g., id.* at ¶ 67.

Once again, S&N seeks dismissal, arguing that the operative pleading is either expressly or impliedly preempted, or otherwise barred under Florida law. *See* Motion.

II. LEGAL STANDARD

Rule 8 of the Federal Rules requires a pleading to contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although a complaint "does not need detailed factual allegations," it must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (explaining that Rule 8(a)(2)'s pleading standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation"). In the same vein, a complaint may not rest on "'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557 (alteration in original)). These elements are required to survive a motion brought under Rule 12(b)(6) of the Federal Rules of Civil Procedure, which requests dismissal for "failure to state a claim upon which relief can be granted."

When reviewing a motion under Rule 12(b)(6), a court, as a general rule, must accept the plaintiff's allegations as true and evaluate all plausible inferences derived from those facts in favor of the plaintiff. *See Chaparro v. Carnival Corp.*, 693 F.3d 1333, 1337 (11th Cir. 2012); *Miccosukee Tribe of Indians of Fla. v. S. Everglades Restoration Alliance*, 304 F.3d 1076, 1084 (11th Cir. 2002); *AXA Equitable Life Ins. Co. v. Infinity Fin. Grp., LLC*, 608 F. Supp. 2d 1349, 1353 (S.D. Fla. 2009) ("On a motion to dismiss, the complaint is construed in the light most favorable to the non-moving party, and all facts alleged by the non-moving party are accepted as

true."). Accordingly, a court considering a Rule 12(b) motion is generally limited to the facts contained in the complaint and attached exhibits, including documents referred to in the complaint that are central to the claim. *See Wilchombe v. TeeVee Toons, Inc.*, 555 F.3d 949, 959 (11th Cir. 2009); *Maxcess, Inc. v. Lucent Technologies, Inc.*, 433 F.3d 1337, 1340 (11th Cir. 2005) ("[A] document outside the four corners of the complaint may still be considered if it is central to the plaintiff's claims and is undisputed in terms of authenticity.") (citing *Horsley v. Feldt*, 304 F.3d 1125, 1135 (11th Cir. 2002)).

However, although a court is required to accept all of the allegations contained in the complaint and exhibits attached to the pleadings as true, this tenet is inapplicable to legal conclusions. *Iqbal*, 556 U.S. at 678; *Thaeter v. Palm Beach Cnty. Sheriff's Office*, 449 F.3d 1342, 1352 (11th Cir. 2006). The Supreme Court was clear that courts "are not bound to accept as true a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555.

III. DISCUSSION

A. Relevant Law and the MDA Framework

The Court has already reviewed the applicable law at length and, accordingly, merely reincorporates its previous recitation from *Mink v. Smith & Nephew, Inc.*, No. 15-CIV-61210, 2015 WL 7356285, at *4-6 (S.D. Fla. Nov. 18, 2015), herein:

On May 9, 2006, the FDA notified S&N that the BHR System had received conditional approval, and S&N could begin commercial distribution of the device. This approval letter imposed a number of specific requirements pursuant to the Medical Device Amendments ("MDA") to the FDCA, which Congress enacted in 1976 to create a regulatory framework for medical devices. Within this framework, the FDA groups prescription medical devices into three classes. *See* 21 U.S.C. § 360c(a)(1). The BHR System was classified as Class III device, which

must undergo a "rigorous" pre-market approval process before it can be marketed. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18, 128 S. Ct. 999, 169 L. Ed.2d 892 (2008) (citing 28 U.S.C. § 360e(d)) (explaining that the FDA grants PMA approval only when it has "'reasonable assurance' of the device's 'safety and effectiveness'").

The FDA has promulgated numerous regulations regarding PMA requirements for Class III medical devices. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344-47, 121 S. Ct. 1012, 148 L .Ed.2d 854 (2001). These regulations require a PMA applicant to produce comprehensive data from which the FDA can make a reasonable determination of the device's safety and effectiveness, including the human clinical trials, design specifications, manufacturing processes, quality controls, and proposed labeling and advertising. *See* 21 C.F.R. § 814.20; *see also Riegel*, 550 U.S. at 318, 127 S. Ct. 1686 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)).

After PMA approval, the FDA imposes ongoing mandates for manufacturers of Class III devices. A manufacturer may not change "design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness" without first obtaining the FDA's authorization. *Id.* at 319, 127 S. Ct. 1686 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). A manufacturer must receive supplemental approval from the FDA for any changes, and the FDA evaluates any such proposed changes "under largely the same criteria as an initial application." *Id.* (citing 28 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)). "All procedures and actions that apply to a PMA application under [21 C.F.R. §] 814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change." 21 C.F.R. § 814.39(c). Class III devices are also subject to post-approval reporting requirements, including informing the FDA of new studies, investigations, or incidents where the device caused or could have caused serious injury. *See Riegel*, 552 U.S. at 319, 128 S. Ct. 999.

Additionally, manufacturers are required to follow the FDA's Current Good Manufacturing Practice ("CGMP") provisions. *See* 21 C.F.R. § 820.1. The FDA retains the authority to withdraw approval. *See Riegel*, 552 U.S. at 319-20, 128 S. Ct. 999.

Given this underlying regulatory scheme, Congress enacted protection for Class III medical devices. Pursuant to § 360k(a) of the MDA, state-law causes of action against manufacturers of Class III medical devices, like S&N, are expressly preempted to the extent they impose requirements "different from, or in addition to," the requirements of federal law:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device and (2) which relates to the safety or effectiveness of the device or to any other matter included in the requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). The Supreme Court has recently held that this language preempts any state-law claims regarding "the design, testing, inspection, distribution, labeling, marketing and sale of" PMA products. *Riegel*, 552 U.S. at 320, 128 S. Ct. 999 (citing *id.*) (barring a tort claim that applies a state law requirement, which (1) relates to safety or effectiveness, and (2) is "different from, or in addition to, any [applicable federal] requirement"); *see also Byrnes v. Small*, 60 F. Supp. 3d 1289, 1297 (M.D. Fla. 2015) (quoting *Buckman*, 531 U.S. at 349 n.4, 121 S. Ct. 1012) ("[T]he FDCA also impliedly preempts suits by private litigants 'for noncompliance with the medical device provisions.'"). Nevertheless, *Riegel* found that the MDA preemption clause does not apply to a parallel claim. *See Riegel*, 552 U.S. at 330, 128 S. Ct. 999. In other words, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements." *Id.* (citation omitted).

Thus, to the extent that expressed preemption applies, to withstand Defendant's Motion, Eleventh Circuit case law requires Plaintiff to plead that S&N breached federal requirements applicable to BHR and that the breach is parallel to a claim under Florida state law. *See Wolicki–Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). Although *Wolicki–Gables* affirmed a district court opinion in the summary judgment context, the Circuit Court held that the inquiry must start with the pleadings—proper analysis "must first consider whether the [plaintiffs] have demonstrated that they have alleged a parallel claim." *Id.* at 1301. To that end, "'[p]laintiffs cannot simply incant the magic words '[defendants] violated FDA regulations' in order to avoid preemption.'" *Id.* (quoting *In re Medtronic Inc.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)). Rather, "[i]n order for a state requirement to be parallel to a federal requirement, . . . the plaintiff must show that the requirements are '*genuinely* equivalent.' State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Id.* at 1300 (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)) (emphasis in original); *see Llado-Carreno v. Guidant Corp.*, No. 09–20971–CIV, 2011 WL 6223409, at *5 (S.D. Fla. May 16, 2011) ("Parallel claims must be specifically stated in the initial pleadings.").

Wolicki-Gables involved a patient who developed complications after undergoing surgery to implant an allegedly defective drug delivery pump system for treatment of chronic pain. 634 F.3d at 1301. The patient, along with her husband, brought a negligence and strict products liability action against the manufacturer of the pump system and related companies. *Id.* After analysis of Florida state laws concerning "(1) strict liability for manufacturing and design defect and failure to warn, and (2) concerning liability for negligent design, manufacture and assembly," the district court concluded "that the Florida laws corresponding to each of those

claims imposed requirements that were 'different from, or in addition to' the federal requirements established for the" specific device. *Id.* Critically, such claims were expressly preempted because "a factfinder could find liability even if the manufacturer had completely complied with the FDA regulations." *Id.* *Wolicki-Gables* further found that the couple failed to "set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged." *Id.* at 1301-02 (citation omitted). "Because the [plaintiffs] failed to allege facts in their complaint demonstrating the presence of the elements of a parallel claim," the Court concluded that the subject claims were preempted under the MDA. *Id.* at 1302.

Since *Riegel* and *Wolicki-Gables*, trial courts within Florida, and within this District, have dismissed strict liability and negligence claims at the pleadings stage, because Florida state-law on these causes of action "clearly impose[ ] requirements which are 'different from, or in addition to' the federal requirements." *Stokes v. I–Flow Corp.*, No. 6:12–cv–991–Orl–36DAB, 2013 WL 1715427, at *7 (M.D. Fla. Apr. 8, 2013) (granting motion to dismiss); *see Llado-Carreno*, 2011 WL 6223409, at *6 ("Accordingly, the negligence and strict liability claims must be dismissed as preempted by federal law."); *Kaiser v. DePuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1190-91 (M.D. Fla. 2013) (dismissing claims and holding that claims under "state tort law" are preempted when they "involve[ ] requirements that were different from, or in addition to, federal requirements"); *Stanifer v. Corin USA Ltd.*, No. 6:14–cv–1192–Orl–37DAB, 2014 WL 5823319, at *4 (M.D. Fla. Nov. 10, 2014) (granting motion to dismiss under *Riegel* and *Wolicki-Gables*); *Lederman v. Howmedica Osteonics Corp.*, 950 F. Supp. 2d 1246, 1249 (M.D. Fla. 2013) (granting motion to dismiss because "any claim that would require the medical device to be manufactured other than in the manner approved and required by the PMA . . . imposed a requirement 'different from, or in addition to' the PMA requirements"). In other words, "[t]he

preemption provision of the MDA exists to dissuade the possibility of such a conflicting result" as a Florida state law "determination that the product is defective or unreasonably dangerous," though compliant with FDA regulations. *Brown v. DePuy Orthopaedics, Inc.*, 978 F. Supp. 2d 1266, 1272-73 (M.D. Fla. 2013).

Many courts have also dismissed complaints for failure to sufficiently allege a parallel claim under *Wolicki-Gables*. *See, e.g., Llado-Carreno*, 2011 WL 6223409, at *5-6 (dismissing claims as not parallel). In *Llado–Carreno*, the court rejected "general allegations" as "insufficient to satisfy the requisite elements of a parallel claim" when they lacked "any factual detail to substantiate [the] crucial allegation." *Id.* at *5 (quoting *Wolicki-Gables*, 634 F.3d at 1302); *see, e.g., Wheeler v. DePuy Spine, Inc.*, 706 F. Supp. 2d 1264, 1267-68 (S.D. Fla. 2010) ("Plaintiff has not stated a claim for products liability that can proceed, as [p]laintiff has not made a claim premised on a violation of FDA regulations.") (citation omitted); *Lederman*, 950 F. Supp. 2d at 1250 (dismissing claim as not parallel because a plaintiff must plead the specific requirements of *Wolicki-Gables*); *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1198-1201 (M.D. Fla. 2013) (dismissing claim as not parallel); *Kaiser*, 944 F. Supp. 2d at 1192 (dismissing claims as not parallel because they failed to "identify any particular federal specification or specific PMA requirement or FDA regulation that [d]efendant violated"); *see also Leonard v. Medtronic, Inc.*, No. 1:10–CV–03787–JEC, 2011 WL 3652311, at *6 n.5 (N.D. Ga. Aug. 19, 2011) ("[T]he Court must apply Eleventh Circuit law, which requires more than a general allegation of an FDA violation to state a valid parallel claim.").

It is through this lens that the Court reviews Mink's Second Amended Complaint. After review, it is clear that Mink's claims must be dismissed.

B. Negligence (Count I)

A district court attempting to ascertain whether a state-law claim is expressly preempted applies a two-pronged inquiry. First, the district court must "determine whether the Federal Government has established requirements applicable [to the device]." *Wolicki-Gables*, 634 F.3d at 1301 (quoting *Riegel*, 552 U.S. at 321-22, 128 S. Ct. 999). If the device is governed by federally-enacted requirements, "[the court] must then determine whether the [plaintiff's] common-law claims are based upon [state law] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* (quoting *Riegel*, 552 U.S. at 321-22, 128 S. Ct. 999). There can be no dispute that the FDA's premarket approval process "imposes 'requirements' under the MDA which are specific to individual devices." *Id.* (internal quotation and citation omitted); *see Byrnes v. Small*, 60 F. Supp. 3d 1289, 1296 (M.D. Fla. 2015) (finding first prong of express preemption analysis automatically satisfied where device was approved through PMA process). As noted, 21 U.S.C. § 360k(a) preempts all claims which (a) relate to the safety or effectiveness of a medical device, and (b) are "different from, or in addition to, any [applicable federal] requirement." *See Riegel*, 552 U.S. at 330, 128 S. Ct. 999 (citation omitted). Thus, only Mink's claims which properly plead parallel claims will survive. *See id.*

Additionally, "the FDCA [ ] impliedly preempts suits by private litigants 'for noncompliance with the medical device provisions.'" *Byrnes*, 60 F. Supp. 3d at 1297 (quoting *Buckman*, 531 U.S. at 349 n.4, 121 S. Ct. 1012). This is because 21 U.S.C. § 337(a) mandates that all actions to enforce FDA requirements "shall be by and in the name of the United States." *Id.* (quoting 21 U.S.C. § 337(a)); *see also In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (noting that suits over conduct purportedly violating

the FDCA is impliedly preempted under *Buckman*). The Eighth Circuit has succinctly explained the interaction between *Riegel* and *Buckman* as follows:

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

In re Medtronic, 623 F.3d at 1204 (citation omitted, emphasis in original). "[W]hen Sections 337(a) and 360k(a)—as construed in *Buckman* and *Riegel*, respectively—are read together, nearly all types of claims concerning FDA-approved medical devices are preempted[.]" *In re Medtronic*, 592 F. Supp. 2d at 1161.

"To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated." *Wolicki-Gables*, 634 F.3d at 1301 (citation and quotation omitted). Initially, Mink's negligence claim was predicated upon S&N's purported violations of a laundry list of related federal regulations, including 21 C.F.R. §§ 820.30(f) and (g), 820.80(c) and (d), 820.100, and 820.198. *See* Amended Complaint ("Am. Compl."), ECF No. [6] at ¶¶ 31-38. Unlike *Wolicki-Gables* and his initial pleading, Mink's present allegations contain a notable increase in specificity. *Compare* Am. Compl. at ¶ 40 *with* SAC at ¶ 51. Mink now incorporates additional provisions; however, Mink has eliminated specific references to particular subsections of the regulations S&N purportedly violated. *See* SAC at ¶¶ 44-48, 51, 59. In fact, Paragraph 51 of the Second Amended Complaint includes a smattering of various violations of 21 C.F.R. §§ 814.82, 814.84, 820.30, 820.80, 820.100, and 820.198, specifically, that S&N:

> (a) failed to conduct an adequate study of the long-term safety and effectiveness of the system in an initial study conducted in the

United Kingdom, failed to investigate previously-revealed adverse effects of the BHR System, and failed to report these adverse effects to the FDA;

(b) failed to implement an adequate and proper training program for physicians using the BHR System;
(c) failed to conduct a meaningful study on the learning curve and training program of physicians in the United States, and failed to select physicians from geographically and professionally diverse settings and overstated the training they received;
(d) failed to submit thorough and sufficiently detailed annual-post approval reports that included bibliographies and summaries of unpublished reports and data from the field, and failed to accurately report the state of science or the symptoms being experienced by patients in the field;
(e) failed to timely submit adverse reaction and device defect reports to the FDA;
(f) failed to submit device reports when it knew that the BHR System was causing serious injuries in the field;
(g) failed to take other remedial actions including conducting additional investigations, initiating voluntary recalls, or informing the FDA and the medical community about the issues with the BHR System;
(h) failed to comply with the specifications set forth in the PMA as evidenced by the defective manufacture of the metal used in the BHR resulting in increased exposure to cobalt and other metals;
(i) failed to maintain adequate and thorough quality assurance and evaluative systems that would have detected the issues;
(j) [This section intentionally left blank.]
(k) failed to identify potential causes of the quality problems in its work operations, quality audit reports, service records, etc.; and
(l) failed to not deviate from the conditions set forth in the PMA generally.

See id. at ¶ 51.[2]

Although Mink's allegations of negligence span seventeen pages, they can be summed up rather succinctly: they are related to S&N's failure to comply with the mandates of the PMA. In contrast to Mink's initial vague allegations, the new allegations are sufficiently specific to

[2] With the exception of original subparagraph (j), which is duplicative of the allegations in original subparagraph (i), the numbering of these assertions as recited herein corresponds with the numbering presented in Paragraph 51.

comport with the requirement that a parallel claim set forth facts "pointing to specific PMA requirements that have been violated." *Wolicki-Gables*, 634 F.3d at 1301 (citation and quotation omitted). Thus, S&N's characterization of the seventeen pages of allegations as "conclusory" is inaccurate. Further, Mink's allegations are, in fact, device specific.[3] The fact that these additional allegations were previously raised in opposition to S&N's original motion to dismiss, see Mink's Original Response, ECF No. [20] at 5-6, does not mean they were rejected by the Court as inadequate at that time.[4] A plaintiff "may not amend his complaint through new allegations raised when responding to a motion to dismiss." *Wennersten v. Commercial Diver Servs., N.A. Inc.*, No. 12-60975-CIV, 2012 WL 3230419, at *1 n.1 (S.D. Fla. Aug. 6, 2012) (citing *Bruhl v. PriceWaterhouseCoopers Int'l*, No. 03–23044, 2007 WL 997362, at *4 (S.D. Fla. Mar. 27, 2007; *Walker v. City of Orlando*, No. 07–651, 2007 WL 1839431, at *5 (M.D. Fla. Jun. 26, 2007)). Thus, the initial impropriety of Mink's argument in responding to Defendant's original motion does not repudiate the viability of such allegations now.

More to the point, this increase in specificity means that cases such as *Wolicki-Gables* and *Llado-Carreno* lose their persuasive power. As noted, the Courts in these cases concluded that the plaintiffs had failed to state a parallel claim where the allegations failed to "set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged." *Id.* at 1301-02; *Llado-Carreno*, 2011 WL 6223409, at *5-6 ("Here, Plaintiff simply

[3] For instance, Mink's accusation that S&N failed to comply with 21 C.F.R. §§ 814.82 and 814.84 by failing to conduct a study of the long-term effectiveness of the BHR System in the United Kingdowm based upon the experiences of the first 350 consecutive patients, is incredibly device specific. Nothing in either § 814.82 or § 814.84 impose such a specific requirement. Rather, these requirements stem from the BHR's PMA Approval.

[4] Such allegations are admittedly drawn from a related action filed by the plaintiffs in *Williams v Smith & Nephew*, Case No. 1:14-cv-03138-CCB (Md.). *Id.* at 5 n.2. Indeed, Mink improperly includes reference to the *Williams* plaintiff. *See* SAC at ¶ 51.b. While this fact calls into question the validity of such allegations, the Court must, nonetheless, accept them as true.

alleges the devices did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices. These general allegations are insufficient to satisfy the requisite elements of a parallel claim, as Plaintiff fails to provide any factual detail to substantiate the crucial allegation." (internal formatting, quotations, and citations omitted)). *Marmol* and *Byrnes* also are of diminished use here. In *Byrnes*, the plaintiff's cause of action was found to be expressly preempted because, among other things, the plaintiff had not identified any federal requirement requiring the defendant to take the action the plaintiff claimed it failed to take. *See* 60 F. Supp. 3d at 1297. Similarly, in *Marmol*, the plaintiff conceded that the violations complained of were not contained in the PMA documents. *See* 2015 WL 5664890, at *5-6. *McClelland* is also rendered unpersuasive on this point. There, the plaintiff alleged that the defendant breached its duty by failing to provide the plaintiff with a warning of the dangers of the product. *See* 944 F. Supp. 2d at 1199. The court found the claim to be expressly preempted as the plaintiff was unable to direct the court to "any statute or regulation which impose[d] a duty on the manufacturer to inform *patients* about such incidents"; the reporting requirements decreed that incidents were to be reported *to the FDA*. *Id.* at 1199-1200 (emphasis in original). In contrast, Mink's allegations set forth the specific PMA requirement violated and how such requirements were violated.

Nevertheless, the second element of the *Riegel* analysis requires the Court to assess "whether [Mink's] common-law claims are based upon [state law] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *See Wolicki-Gables*, 634 F.3d at 1301 (quoting *Riegel*, 552 U.S. at 321-22, 128 S. Ct. 999). Regardless of whether Mink's negligence claim is parallel and, therefore, not expressly preempted, it is evident that the claim is barred under Florida law.

Mink's negligence action is, in essence, an action seeking to enforce the PMA requirements against S&N. Previously, this Court discussed the case of *Wheeler v. DePuy Spine, Inc.*, 706 F. Supp. 2d 1264 (S.D. Fla. 2010). *See Mink*, 2015 WL 7356285, at *7. In *Wheeler*, the plaintiff attempted to state a parallel claim by alleging that the defendant violated certain requirements imposed by the FDA pursuant to the PMA process. 706 F. Supp. 2d. at 1269. The court rejected the allegations in their entirety:

> Even if these [ ] characteristics were to be construed as federal requirements, [p]laintiff has failed to assert a state law authorizing such claims and, therefore, his claim must fail.... Whether these claims are characterized as negligent design, manufacture, or sale of the product, Florida law does not authorize the only type of "negligence" claims that might survive the MDA, i.e., a claim based on violation of federal requirements.

706 F. Supp. 2d. at 1269-70. The court reasoned that "the MDA shields manufacturers of FDA-approved medical devices from state products liability laws absent a specific state law providing a damages remedy for claims premised on violations of FDA regulations." *Id.* at 1268. As a result, "common law products liability or negligence actions—i.e., actions not based on a 'parallel' requirement adopted by a state—are preempted by the MDA." *Id.* at 1270. The "claims are preempted to the extent that they are not based on violations of federal requirements, and the claims fail to the extent that they are based on violations of federal requirements, as Florida law does not provide such a remedy." *Id.* As noted by the court in *Marmol*, "every court in this circuit to have directly addressed this issue has 'consistently held that private actions . . . that seek to enforce violations of FDA regulations [including PMA requirements] are barred because Florida does not recognize such causes of action.'" 2015 WL 5664890, at *7 (quoting *Kaiser*, 944 F. Supp. 2d at 1192, and citing *Jackson v. St. Jude Med. Neuromodulation Div.*, No. 2:14-cv-717-FtM-38DNF, 2015 WL 1456650, at *7 (M.D. Fla. Mar. 30, 2015); *Byrnes*, 60 F.

Supp. 3d at 1297; *Brown v. DePuy Orthopaedics, Inc.*, 978 F. Supp. 2d 1266, 1275 (M.D. Fla. 2013); *McClelland v. Medtronic, Inc.*, No. 6:11-CV-1444-ORL-36, 2012 WL 5077401, at *6 (M.D. Fla. Sept. 27, 2012); and *Wheeler*, 706 F. Supp. 2d at 1268, 1269-70) (holding that "[e]ven if Plaintiff could properly allege a sufficient, parallel claim based on violations of the PMA specifications or federal regulations, Florida law does not permit a private action to enforce violations of FDA requirements.");[5] *see generally Wheeler*, 706 F. Supp. 2d at 1270 ("Florida law does not authorize the only type of 'negligence' claims that might survive the MDA, i.e., a claim based on violation of federal requirements. . . . Plaintiff's negligence claims are pre-empted to the extent that they are not based on violations of federal requirements, and the claims fail to the extent that they are based on violations of federal requirements, as Florida law does not provide such a remedy."). Once again, Mink does not point to, and the Court is unaware of, any Florida law that requires a medical-device manufacturer to include a specific patient in a product study, fund patient monitoring, report defects or adverse effects to the FDA, or the like. Accordingly, such claims flounder under the applicable law.

Along these same lines, Mink's claim is impliedly preempted. The entirety of the aforementioned allegations relate to S&N's specific failure to comply with myriad aspects of the PMA Approval Letter and other obligations required by the FDA and the FDCA. As noted by the PMA Approval Letter, "distribution of a device that is not in compliance with these conditions is a violation of the [FDCA]." PMA Approval Letter at 5. Thus, the multitude of purported violations—including, *inter alia*, S&N's failure to comply with the PMA's study

[5] The Eleventh Circuit in *Wolicki-Gables* did not address the issue of whether Florida law recognized private actions for violations of FDA regulations. *See* 634 F.3d at 1302 ("Because the [plaintiffs'] claims are preempted, we do not address [defendant's] assertion that private actions brought for violations of the FDA regulations are barred pursuant to 21 U.S.C. § 337(a).")

requirements, training programs, adverse device reporting requirements, etc.—are purported violations of S&N's obligations under the FDCA. Indeed, Mink admits that the crux of his negligence claim is S&N's violations of the PMA standards. *See* Pl. Resp. at 9, 12. On this point, cases such as *McClelland* and *Byrnes* retain their value.

In *Buckman*, "the United States Supreme Court construed § 337(a) as impliedly preempting suits by private litigants 'for noncompliance with the medical device provisions.'" *McClelland*, 944 F. Supp. 2d at 1200 (quoting 531 U.S. 341, 349 n. 4, 121 S. Ct. 1012). In *McClelland*, the Middle District of Florida concluded that a claim predicated upon violations of the FDCA and its implementing regulations, specifically, those requiring the defendant to inform the FDA about adverse incidents, were impliedly preempted as it was a thinly veiled attempt to "recast a claim for violation of the FDCA as a state-law negligence claim." *Id.* at 1200-01. Similarly, in *Byrnes*, the plaintiff's claim based on failure to adhere to FDCA requirements was impliedly preempted as the plaintiff failed to identify any consistent state law duty. *See* 60 F. Supp. 3d at 1297, 1300 ("[T]o the extent that the claim is premised on [plaintiff's] failure to comply with federal law and regulations [ ], it is impliedly preempted."). In short, "to the extent that [a] [p]laintiff's negligence claim can be construed as alleging a breach of duty owed by [a] [d]efendant to the FDA, such a claim is impliedly preempted by § 337(a)." *See McClelland*, 944 F. Supp. 2d at 1200; *In re Medtronic*, 623 F.3d at 1204 (citation omitted) (noting that a suit filed "because the conduct violates the FDCA . . . would be impliedly preempted under *Buckman*") (citation and emphasis omitted); *see also Jackson*, 2015 WL 1456650, at *7 (finding negligence

claim impliedly preempted where plaintiff based claim on allegations that the device "failed to meet FDA requirements").[6]

While Mink recognizes that a parallel claim may survive preemption under § 360k and addresses the express preemption argument in full, see Pl. Resp. at 11-12 (citing *Riegel*, 552 U.S. at 330, 128 S. Ct. 999), he entirely fails to engage S&N's arguments as to implied preemption. Nevertheless, it is evident that a plaintiff may not "attempt to recast a claim for violation of the FDCA as a state-law negligence claim" simply by pleading it as such. *McClelland*, 944 F. Supp. 2d at 1200 (finding negligence claim based on failure to report adverse events to the FDA to be impliedly preempted by § 337(a)); *see also Byrnes*, 60 F. Supp. 3d at 1297 (finding the same). This is precisely what Mink has done here. Although the allegations note with specificity the provisions violated and the manner in which they were violated, Mink, in substance, alleges that S&N violated the FDCA and its implementing regulations through these various failures, including failures related to reporting deficiencies, failures concerning manufacture in conformity with the PMA requirements, failure to file adverse incident reports and advise the larger medical community of possible dangers, and other general reporting failures. *See* SAC at ¶ 51. The mere fact that Mink prefaces all such allegations with the disclaimer that they are brought "only to the extent that they are parallel to and not different from or in addition to the

[6] Further, to the extent these allegations may be construed as a failure to warn claim or, alternatively, for a manufacturing defect claim, such claims are also impliedly preempted. *See Marmol*, 2015 WL 5664890, at *8-9 (noting that "each court in this circuit that has addressed the viability of a failure-to-warn claim in relation to a medical device governed by the PMA process, has determined that the claim is impliedly preempted because Florida law lacks a parallel duty to file adverse reports with the FDA" and holding that the plaintiff's failure-to-warn claim "premised upon an FDA-reporting requirement that is not paralleled by a Florida-law duty" is impliedly preempted) (citations omitted); *see also Byrnes*, 60 F. Supp. 3d at 1300. This Court previously cautioned Mink that "any allegations of a failure to warn . . . would also be preempted." *Mink*, 2015 WL 7356285, at *8 (citations omitted). Mink's allegations that S&N should have alerted the FDA and the general public fall into this category.

requirements of federal law," SAC at ¶ 51, does not negate the fact that the allegations are a plain attempt at circumventing 21 U.S.C. § 337(a).

Admittedly, the Court is mildly perplexed as to what manner of claim would make it through the "narrow gap," described by the Eighth Circuit in *In re Medtronic*, 623 F.3d at 1204. Nevertheless, after canvassing the binding and persuasive authority submitted in support of S&N's Motion, it is clear that Mink's claim cannot fit.

C. Strict Products Liability (Count II)

Like Mink's claim for negligence, Mink's claim for strict products liability is also predicated upon a violation of certain federal regulations, including, "21 C.F.R. § 814.80 [and] other applicable federal regulatory and statutory laws." *See* SAC at ¶ 59. Notably, Mink's theory points to the fact that S&N manufactured the BHR System different from the manufacturing specifications contained in the PMA. *See id.* For the same reasons noted in the preceding Section, Mink's claims based on a manufacturing defect are also impliedly preempted.

In *Marmol v. St. Jude Med. Ctr.*, No. 8:15-CV-1276-T-30TGW, 2015 WL 5664890 (M.D. Fla. Sept. 24, 2015), the plaintiff brought a products liability claim for, among other things, the defendant's failure to manufacture the PMA-approved product at issue consistent with specifications. *See id.* at *1. Not only did the Middle District conclude that the plaintiff's claims were "not permitted under Florida law," but also determined that they were impliedly preempted as there is "no private right of action under the FDCA." *Id.* at *7 n.6 (citing *Buckman*, 531 U.S. at 352-53). Similarly, here, Mink's claim for products liability asserts that S&N failed to comply with the requirements of the PMA, specifically, the regulation providing that "[a] device may not be *manufactured*, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the

device." 21 C.F.R. § 814.80 (emphasis added). As previously noted, the FDCA impliedly preempts suits by private litigants "for noncompliance with the medical device provisions." *Byrnes*, 60 F. Supp. 3d at 1297 (quoting *Buckman*). As a result, Mink cannot maintain an action where the exclusive foundation for that action is noncompliance with the medical device provisions. *See Marmol* at *7 n.6.

D. Breach of Contract (Count III)

Under Count III, Mink states that his termination from the BHR Study breached the contract created by the Consent to Participate Form. *See* SAC at ¶¶ 66-80 ("By terminating him as a Study Participant in the first year following Plaintiff's surgery, Defendant breached its oral contractual obligation to Plaintiff to examine, test, x-ray and take blood samples to monitor the effects of the BHR on the Plaintiff, and to pay the costs associated with the required procedures, including metal on metal assessments of renal function, samples of blood to measure metal ions in the blood and body and other tests to evaluate the BHR system. Said contract being memorialized in the 'Consent to Participate' [ ] and in subsequent written communications in which [S&N] gave written notice terminating him from the [S]tudy."). In pleading this claim, Mink asserts that Dr. Weisstein was acting as S&N's "expressed and implied agent" and, further, avers that S&N "ratified" such representations and commitments thereafter. *See id.* at ¶¶ 66-67.

Mink's amended allegations do nothing to ameliorate the issues highlighted by this Court when considering Mink's First Amended Complaint. *Mink*, 2015 WL 7356285, at *6. First, Mink neither alleges facts establishing a contract between himself and S&N, nor facts demonstrating a breach of any provision of the agreement. *See Brown v. Capital One Bank (USA), N.A.*, 2015 WL 5584697, at *3 (S.D. Fla. Sept. 22, 2015) ("Plaintiffs must allege the following elements to state a claim for breach of contract: (1) a valid contract; (2) a material

breach; and (3) damages. In order to allege a material breach in accordance with the pleading standards required under the Federal Rules of Civil Procedure, the plaintiff must allege which provision of the contract has been breached.") (citations omitted). Even assuming, *arguendo*, that Dr. Weisstein was acting as S&N's agent,[7] nothing in the Consent to Participate Form requires that Mink be maintained as a patient in the BHR Study.

Second, and more critically, Count III is expressly preempted. As with Plaintiff's negligence claim, the FDA's premarket approval process "imposes 'requirements' under the MDA which are specific to" the BHR System. *See Wolicki-Gables*, 634 F.3d at 1301 (citation omitted). In order to allege a parallel state law claim, Mink must point to "specific PMA requirements that have been violated." *Id.* (citation and quotation omitted). Yet he fails to pinpoint what provision his termination from the Study violates. Moreover, Mink is unable to identify whether the FDCA or PMA prohibits a manufacturer from terminating a study participant. Section 360k(a) preempts all claims which (a) "relate[] to the safety or effectiveness of the device or to any other matter included in the requirement applicable to the device under th[e] [FDCA]," 21 U.S.C. § 360k(a), and (b) are "different from, or in addition to, any [applicable federal] requirement." *Riegel*, 552 U.S. at 330, 128 S. Ct. 999 (citation omitted). If the FDCA and its affiliated regulations do not forbid a study participant's early termination, any state law that does forbid early termination necessarily imposes a requirement that is "different

[7] S&N continues to challenge the adequacy of this allegation and rightfully so. *See* Motion at 17-18. Dr. Weisstein signed the Consent to Participate Form not as S&N's agent but, rather, as the "Investigator (or Individual Facilitating Consent Process). *See* Consent to Participate Form at 10. Further, 21 C.F.R. § 812.100 requires the investigator, not the manufacturer to obtain the patient's consent. Nevertheless, the Court assumes, for purposes of this Motion, that such allegations are sufficient as other reasons warrant the dismissal of this claim.

from, or in addition to" the relevant federal requirements. *See id.* Consequently, the asserted state-law obligation is expressly preempted under 21 U.S.C. § 360(k) and related jurisprudence.[8]

E. Misrepresentation (Count IV)

As with his breach of contract claim, Mink's misrepresentation claim finds its roots in S&N's representations that he would be included in the BHR Study for a period of ten (10) years. *See* SAC at ¶¶ 81-89. Mink's misrepresentation claim succumbs to the same legal theories which force the dismissal of the previously-discussed claims. *Supra* Sections III.B-D.

IV. CONCLUSION

This Court is sympathetic to Mink's plight. Nevertheless, binding precedent once again requires that his claims merit dismissal, this time with prejudice as it is evident that Mink cannot present claims that are both valid under Florida law and escape preemption's firm grip. *See Stevens v. Premier Cruises, Inc.*, 215 F.3d 1237, 1239 (11th Cir. 2000) (noting that "[a] district court, before dismissing a complaint with prejudice because of a mere pleading defect, ordinarily must give a plaintiff *one opportunity* to amend the complaint and to cure the pleading defect" (emphasis added and citation omitted)). It is, therefore, **ORDERED AND ADJUDGED** that Defendant Smith & Nephew, Inc's Motion to Dismiss Plaintiff's Second Amended Complaint, **ECF No. [32]**, is **GRANTED**. Plaintiff's Second Amended Complaint, **ECF No. [29]**, is **DISMISSED WITH PREJUDICE**, and the Clerk is instructed to **CLOSE** this case.

[8] As a final note, this claim is also subject to implied preemption in the sense that it also seeks to privately enforce the FDA's federal regulatory scheme. Claims sounding in private enforcement are impliedly preempted. *See, e.g., Leroy v. Medtronic, Inc.*, No. 3:14cv284/MCR/CJK, 2015 WL 4600880, at *3 (N.D. Fla. June 29, 2015).

DONE AND ORDERED in Miami, Florida this 11th day of March, 2016.

BETH BLOOM
UNITED STATES DISTRICT JUDGE

Copies to:
Counsel of Record